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Future regulation of assistive technology

Submission to TGA consultation

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This report has been developed through Engineers Australia's member-delivered policy and advocacy by the College of Biomedical Engineering

Submission: Future regulation of assistive technology

Authors: Friesen Osborne, E. & Brown, I., National Committee on Rehabilitation Engineering, Biomedical College

The document can be downloaded at engineersaustralia.org.au

Engineers Australia
11 National Circuit, Barton ACT 2600
Tel: +61 2 6270 6555
Email: policy@engineersaustralia.org.au

engineersaustralia.org.au

Contents

Introduction

Medical device regulation is recognised to be a key foundation for a safe and effective Medical Device industry in Australia. Engineers Australia's Biomedical College appreciates that the Therapeutic Goods Administration (TGA)'s task of ensuring regulations remain relevant to the contemporary landscape is an ongoing challenge of competing interests.

A representative group of the Engineers Australia's Biomedical College has reviewed the proposed changes to the regulation of assistive technologies and has prepared the following submission based on the questions posed in the consultation paper, supported by general comments.

About Engineers Australia

As Australia's national body for engineering, we are the voice and champion of our 120,000-plus members. We provide them with the resources, connections, and growth they need to do ethical, competent and high-value work in our communities.

A mission-based, not-for-profit professional association, Engineers Australia is constituted by Royal Charter to advance the science and practice of engineering for the benefit of the community. We back today's problem-solvers, so they can shape a better tomorrow.

Engineers Australia's national College of Biomedical Engineering (Biomedical College), and its specialist committee, the National Committee on Rehabilitation Engineering (NCRE) have developed this response to the Australian Government's Therapeutic Goods Administration. The NCRE is an expert committee of the Biomedical College, with specific focus on development and delivery of Assistive Technologies. [1] As an expert committee, NCRE advises both the Biomedical College, and Engineers Australia, on matters specific to rehabilitation engineering and Assistive Technology. The College's membership reflects the broad spectrum of engineering perspectives, including engineers working clinically and at point-of-care, across medical device design, development, manufacture, supply and life cycle management, in research and research translation, across regulatory compliance, standards and policy development, and in education and training.

[1] Engineers Australia Biomedical College (accessed November 2024) https://www.engineersaustralia.org.au/engineering-communities/colleges-and-college-national-committees/biomedical-college/national

Preliminary discussion

Definition of assistive technologies

The Consultation paper defines 'assistive technologies' as:

> *products that are used to maintain or improve an individual's functioning and independence, thereby promoting their well-being*[2]

Engineers Australia broadly supports reference to and use of internationally recognised Standards in current and future regulation of assistive technologies. To this end, and for the purpose of this consultation response, Engineers Australia utilises the term 'assistive technologies' throughout this submission (see Appendix). Consistent with the consultation paper, and with ISO 9999: 2022 Assistive products for persons with disability – Classification and terminology and AS/NZS ISO 9999: 2023 (see Appendix), Engineers Australia defines 'assistive technologies' as:

> *products [including devices, goods, instruments, systems, and software] that maintain, improve, or optimise a person's functioning.*

According to the World Health Organization (WHO), assistive technologies can help maintain or improve an individual's functioning in relation to cognition, communication, hearing, mobility, self-care and vision. Beyond promoting wellbeing, assistive technologies have potential to enable an individual's health, inclusion and participation. WHO states that assistive technologies are most needed by:

- older people
- children and adults with disabilities
- people with long term health conditions such as diabetes, stroke and dementia.[3]

However, WHO further contends that most people will need, or would benefit from, assistive technologies at some point in their lives, especially as they age. While some people may require assistive technologies for a longer period or throughout their lifespan, some will require it temporarily, such as after an accident or illness. Further, assistive technologies may be utilised across broad and diverse environments of use, consistent with a person's inclusion and participation goals.

For these reasons, Engineers Australia strongly supports use of internationally accepted definitions of assistive technologies, including those in published Standards, that do not specify or reference a specific group of users, for example 'people with disability', or an environment or place of use, like 'household'. Rather, definitions should focus on the physical or mechanical effect on the human body, as they do for other medical devices regulated by TGA.[4]

Assistive technologies as medical devices

AS/NZS ISO 9999: 2023 (and *ISO 9999:2022*) is a classification and terminology standard for assistive products. It does not, and does not seek to, determine if products defined within the Standard are medical devices. While the definitions of assistive technologies and medical devices may overlap, it

[2] Therapeutic Goods Administration. 'Consultation: Proposed changes to the regulation of assistive technologies' *Department of Health and Aged Care, Australian Government* (July 2024) https://consultations.tga.gov.au/tga/consultation-future-regulation-of-assistive-techno/supporting_documents/TGA%20Public%20Consultation%20%20Future%20regulation%20of%20assistive%20technologies%2022%20July%202024.pdf

[3] World Health Organization. 'Assistive technology' *WHO* (January 2024) https://www.who.int/news-room/fact-sheets/detail/assistive-technology

[4] Therapeutic Goods Administration. 'Product regulation according to risk' *Department of Health and Aged Care, Australian Government* (accessed November 2024) https://www.tga.gov.au/product-regulation-according-risk
Therapeutic Goods Administration. 'Overview of medical devices and IVD regulation' *Department of Health and Aged Care, Australian Government* (accessed November 2024) https://www.tga.gov.au/overview-medical-devices-and-ivd-regulation

should not be assumed that assistive technologies identified and classified within the Standard are medical devices according to Australian regulations.

Consistent with current regulatory approaches, any and all assistive technologies should be individually assessed against the definition of medical devices in section 41BD of the Therapeutic Goods Act 1989, and further informed by the Therapeutic Goods (Medical Devices - Specified Articles) Instrument 2020.

Risk levels of assistive technologies

As AS/NZS ISO 9999: 2023 (and ISO 9999: 2022) demonstrates, the term 'assistive technologies' encompasses a diverse range of products, devices, goods, instruments, systems, and software.

Some assistive technologies, such as adaptive cutlery, long handled shoehorns, and adapted furniture, are simple and present low or negligible risks to individual users and the public. There is little to no public benefit in regulating these products as medical devices. Other assistive technologies, including mobility aids, communications devices, and hearing aids, are potentially complex and present non-trivial risks to individual users and the public. There are sensible and practical reasons to regulate these products as medical devices. Between these two extremes lies a diverse array of products, devices, goods, instruments, systems, and software, with a similarly diverse range of risk profiles. It neither makes sense for the TGA to regulate all assistive technologies, nor to exclude all assistive technologies from TGA regulatory oversight.

Consistent with the current risk-based approach to medical device regulation, Engineers Australia contends that assistive technologies should be classified based on risk levels. Adoption of an evidence-based framework for further stratifying risk levels within this Low risk level classification should be considered, i.e. within Class I. Many assistive technologies currently defined in AS/NZS ISO 9999: 2023 (and ISO 9999: 2022) present a low risk level, and classification of Class I, when assessed according to the TGA's classification approach[5]. AS/NZS ISO 9999: 2023 (and ISO 9999: 2022) offers classification and terminology of assistive technologies' function. It does not address risk. Consultations undertaken by the Australian Government in other aspects of assistive technology provision have adopted a three-level risk classification (see Appendix).

Low-risk assistive technologies:

Low-risk assistive technologies are defined as having a low potential for causing harm when used for activities in daily living environments, and when used according to the manufacturer's Instructions for Use. Low risk assistive technologies generally:

- Are simple and relatively low-cost daily living aids that are often mass-produced, and available "off the shelf".
- Require no additional assessment phase to select or match the assistive technologies to a user's needs.
- Have no or few options for configuration and selection (for example, only one size available, or few sizing options) making it easy for a person and their circle of support to assess and select an appropriate solution to optimise functioning or reduce disability.
- Require no consumables or accessories for safe and effective use.
- Require no or minimal set up and/or adaptation (adjustment), without tools, according to the manufacturer's Instructions for Use.

[5] Therapeutic Goods Administration. 'Medical devices overview' *Department of Health and Aged Care, Australian Government* (July 2024) https://www.tga.gov.au/products/medical-devices/medical-devices-overview

- Require no or minimal periodic cleaning, inspection, and basic maintenance. Where basic maintenance is required, this can be completed without tools, according to the manufacturer's Instructions for Use.

Examples of low-risk assistive technologies include adapted cutlery, adapted furniture, and long-handled shoehorns. As these low-risk assistive technologies represent minimal to no risk to the user and to the public, there is little to no public benefit in regulating these products as medical devices.

Under-advice assistive technologies:

Under-advice assistive technologies are defined as those either "specially produced", or "generally available", that would benefit from (written) advice to ensure that they are selected, installed, and/or used correctly by the individual person and their circle of support.

Under-advice assistive technologies generally:

- Have some options for configuring prior to supply, using information supplied by the manufacturer (for example, marketing materials) or be supplied with accessories and/or consumables (for example, wheeled walking frame with seat and /or basket).

- Have scope to be personalised to an individual user (that is, adaptable through adjustments provided by the manufacturer and by following the manufacturer's instructions for use) and / or custom-made or incorporating custom-made components.

- Require set up and/or adjustment with basic tools, according to the manufacturer's Instructions for Use (such as with an Allen key or screwdriver).

- Require periodic cleaning, inspection, and basic maintenance, according to the manufacturer's Instructions for Use, across the useful life.

Under-advice assistive technologies may be adaptable (that is, personalised after they are manufactured) to meet the needs of a specific user / person. They may be appropriate for a gentler regulatory approach that has potential to facilitate quick supply with minimal wraparound services.

'Prescribed' assistive technologies:

'Prescribed' assistive technologies (see Appendix) are complex technologies, or combinations of technologies, that are configured and / or personalised precisely to meet an individual's needs. Assistive technologies in this classification benefit from clinically focused assessment and (written) advice by appropriately qualified and registered allied health, medical, engineering, and/or nursing practitioners, working within their Scopes of Practice.

Some complex assistive technologies solutions, especially those involving a combination of assistive technologies, may require input and advice from an interdisciplinary team of practitioners with clinical and technical expertise, and wraparound services to optimise outcomes for the intended user/s.

Involvement of specialised assistive technologies suppliers is also needed to ensure safe set up and use of the assistive technologies across their useful life. 'Prescribed' assistive technologies generally:

- Are personalised (adapted, patient-matched and / or custom-made) for an individual user, and supplied with accessories and/or consumables necessary for safe and effective use.

- Require set-up, fitting, and / or adjustment with specialist tools, and by appropriately skilled and knowledgeable technical practitioners / personnel along with the 'prescriber'.

- Require periodic cleaning, inspection, maintenance, repairs, replacement of accessories, and adjustment, according to the manufacturer's Instructions for Use, to ensure ongoing safe operation across the useful life.

Response to consultation questions

Proposal 1: Remove the current exclusion

1. Do you broadly agree that the current exclusion for "household and personal aids, or furniture and utensils, for people with disabilities" should be removed?

Engineers Australia broadly agrees that the current exclusion of "household and personal aids, or furniture and utensils, for people with disabilities" is not fit for purpose and should be removed.

However, Engineers Australia has concerns with the possible implementation of Proposal 2 that must be clarified before Proposal 1 can be agreed to without reservation. The proposals have significant overlap with ongoing transition associated with the Personalised Medical Devices regulatory update, and the yet-unannounced outcomes of the 'Proposed changes to the regulation of exempt medical devices and exempt Other Therapeutic Goods'[6] consultation in 2024. The TGA is strongly encouraged to have a more comprehensive alternative in place before adopting Proposal 1 and removing the current exclusion.

2. Why or why not?

The ambiguity in language of Schedule 1, Item 9 reflects the underlying expectations of assistive technologies provision at the time it was adopted. However, it is inadequate for the current market. The language of Schedule 1, Item 9 lacks the clarity and specificity needed to effectively manage the diversity of assistive technologies.

Engineers Australia's rationale for removal of Schedule 1, Item 9 exclusion is as follows:

- **The exclusion as currently written is inconsistent with TGA's approach to medical device regulation.** TGA regulates on the intended purpose as defined by the manufacturer / sponsor. The manufacturer / sponsor decides if their product / device 's intended purpose is "alleviating or compensating for an injury or disability" (s.41BD). Schedule 1, Item 9 does not reference an intended purpose, but rather specifies intended users, for example "people with disabilities" (see Appendix).
- **The exclusion as currently written is inconsistent with international-accepted terminology and definitions of assistive technologies.** Definition of assistive technologies is addressed in the Preliminary Discussion of this submission. While the definitions of assistive technologies and medical devices may overlap, it should not be assumed that all assistive technologies are also medical devices.
- **The exclusion as currently written does not address varying risk profiles of the assistive technologies**. Risk levels of assistive technologies is addressed in the Preliminary Discussion of this submission.
- **The exclusion as currently written is inconsistent with other Items in Schedule 1.** No other Item listed in Schedule 1 includes the qualifier of "person with …", or reference to an intended user. Schedule 1 items are all either named devices with no qualifiers, or devices with an intended use or purpose (for example, 11A mouthguards used in contact sports; 11B ocular prostheses intended by the manufacturer to be used for cosmetic purposes).
- **The exclusion as currently written is incomplete.** By specifically referencing "people with disabilities", Schedule 1, Item 9 does not account for assistive technologies that alleviate or compensate for injury, temporary impairment, or any impairment or injury that is not also defined as 'disability'.

6 Therapeutic Goods Administration. 'Proposed changes to the regulation of exempt medical devices and exempt Other Therapeutic Goods' Department of Health and Aged Care, Australian Government (April 2024) https://consultations.tga.gov.au/tga/proposed-changes-to-exempt-devices-and-otgs/

- **The exclusion as currently written arbitrarily defines assistive technologies in terms of location or type of use**, for example "household" and "personal". These delineations are arbitrary and undefined. They potentially create scenarios where the same assistive technology product could be excluded (as when it is supplied to a user for home use) and not excluded (as when it is supplied to a multi-user setting such as a hospital or group living facility), depending on the environment or context of use.
- **The exclusion as currently written has potential to be inappropriately interpreted.** Engineers Australia is aware of potential for manufacturers / sponsors to designate devices as "assistive technology" and therefore claim exclusion from all regulatory oversight, irrespective of alignment with legislated definitions of a medical device, intended purpose, or associated risk profile. Engineers Australia strongly supports closing this potential loophole in the interests of user and public safety.

3. What would be the financial impact for you if the TGA removed the current exclusion for "household and personal aids, or furniture and utensils, for people with disabilities"? If possible, please provide a breakdown of the impacts (cost, time, types and estimated numbers of impacted products).

Engineers Australia, as the professional body representing individual engineers, is not a manufacturer or sponsor per se, and does not have specific information on potential financial impact of removing the current exclusion. We therefore offer the following insights into cost calculations viewing the regulatory system as a whole.

If Proposal 1 is adopted without either Proposal 2 or any other regulatory changes being implemented (that is that all assistive technologies meeting the definition of a medical device, regardless of risk classification, are subject to regulatory oversight by the TGA), financial impacts would likely be proportional to:

- The number of device types which were no longer excluded,
- The complexity of these device types,
- The complexity of the manufacture and supply chain,
- The associated risks in each stage of the product lifecycle,
- Any existing contractual arrangements or tenders for supply that may otherwise require evidence of regulatory compliance, and
- Additional compliance requirements such as certified quality management systems.

These changes will largely relate to Class I medical devices, as devices presenting higher potential risk should not legitimately be covered by the Item 9 exclusion.

The Preliminary Discussion in this submission offers an overview of risk classifications for assistive technologies. Many assistive technologies identified in AS/NZS ISO 9999: 2023 (and ISO 9999: 2022) are mass produced or generally available, and present low or negligible risks to users and the general population. For most of these assistive technologies, potential risks are sufficiently addressed through a manufacturer's Declaration of Conformity utilising self-certification procedures of Schedule 3, Part 6, clause 6.6,[7] (rather than through conformity assessment procedures of higher-risk classes of medical devices).

[7] Therapeutic Goods Administration. 'Completing a Declaration of Conformity for Class 1 medical devices' *Department of Health and Aged Care, Australian Government* (December 2020) https://www.tga.gov.au/resources/guidance/completing-declaration-conformity-class-1-medical-devices

The self-certification procedures for Declarations of Conformity will still result in increased costs for the manufacturer/sponsor, primarily for preparation and compilation of appropriate documented evidence (including clinical evidence) to satisfy the regulatory obligation to have this ready in case of request.

Additional costs for the manufacturer/sponsor associated with Proposal 1, include:

- Establishment, certification, and ongoing compliance requirements of quality management systems.
- For assistive technologies that are "specially produced" or intended by the manufacturer as personalised (adapted or patient-matched) devices, cost and complexity of generating clinical evidence, including defining a Specified Design Envelope across the six identified parameters (structural, materials, manufacturing, clinical environment, performance, and other parameters). [8]
- Initial and recurring costs for registering these assistive technologies on the Australian Register of Therapeutic Goods (ARTG), plus costs associated with preparing the submission and necessary supporting documentation.

The increased costs will disproportionately affect sole traders, small to medium enterprises (SMEs) that are less able to quickly implement these changes, and cover the costs associated with becoming market ready. Increased costs associated with meeting regulatory requirements will likely to be passed on to consumers through increased pricing, which may negatively impact health and wellbeing outcomes for consumers. Enterprises with existing contractual obligations may be forced to absorb these costs, which may negatively impact on business operations and viability.

The impact of additional regulatory compliance costs on the Australian assistive technologies market should be assessed further, once planned regulatory changes are better defined.

Should Proposal 2 (or a variation thereof) be implemented in conjunction with Proposal 1, the potential increases in cost and burden are likely lessened but are still non-trivial.

4. What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.

Without clarity regarding the full scope of Proposal 2 it is difficult to anticipate what compliance timeframe might be needed.

The proposed regulatory changes in this present consultation have significant overlap with the ongoing transition associated with the 'Personalised Medical Devices' regulatory reforms[9], and the yet-unannounced outcomes of the 'Proposed changes to the regulation of exempt medical devices and exempt Other Therapeutic Goods' consultation in 2024[10]. It would be reasonable to align these, so that all changes come into effect in concert, rather than having overlapping transition timelines. An implementation date of 1 July 2029 provides ample time for the necessary processes to be developed and implemented, regardless of the size, or bureaucratic complexity of the organisation.

[8] Therapeutic Goods Administration. 'Clinical evidence guidelines for medical devices' (p.65-68) *Department of Health and Aged Care, Australian Government* (June 2022) https://www.tga.gov.au/sites/default/files/clinical-evidence-guidelines-medical-devices.pdf

[9] Therapeutic Goods Administration. 'Medical devices reforms: Personalised medical devices' *Department of Health and Aged Care, Australian Government* (November 2024) https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-devices-reforms/medical-devices-reforms-personalised-medical-devices

10 Therapeutic Goods Administration. 'Proposed changes to the regulation of exempt medical devices and exempt Other Therapeutic Goods' Department of Health and Aged Care, Australian Government (April 2024) https://consultations.tga.gov.au/tga/proposed-changes-to-exempt-devices-and-otgs/

Proposal 2: Introduce exemptions for some assistive technologies

5. Are there assistive technology devices that should be granted an exemption in order to reduce regulatory burden for manufacturers and/or sponsors?

With respect to Proposal 2, Engineers Australia seeks urgent clarification on the intention of **exemption** with respect to pre-market assessments. The consultation paper states:

> *"Exempt medical devices are still regulated by the TGA as medical devices, but they are not required to undergo a pre-market assessment or be included in the ARTG before they are imported, exported or supplied in Australia"*

This statement regarding "pre-market assessment" appears inconsistent with the TGA's advice published elsewhere, including guidance on conformity assessment procedures and manufacturers' Declaration of Conformity.[11] The self-certification procedures for Class I non-measuring, non-sterile medical devices is described as a conformity assessment procedure[12], and in the view of Engineers Australia, a pre-market assessment activity.

TGA communications are clear that exemption does not absolve manufacturers from requirements to meet all regulatory obligations, including conformity assessments:

> *"While exempt products are not required to be included in the ARTG, they are not excluded from regulation and must generally still meet all regulatory obligations under the Therapeutic Goods Act 1989, including:*
>
> - *Ensuring the device(s) meets all relevant Essential Principles, including supplying the devices with adequate labelling and Instructions For Use.*
> - *Applying appropriate conformity assessment procedures to the device at all times.*
> - *Ensuring advertising complies with the advertising requirements.*
> - *Reporting adverse events."*[13]

The TGA has previously flagged low rates of awareness and compliance with regulatory requirements, owning to incorrect assumptions that "exempt" means "excluded" from all regulation by the TGA.[14] Engineers Australia agrees that disambiguation between "exempt" and "excluded" is a recognised issue, particularly for sponsors with limited experience engaging with the TGA. Further detail is required to outline how the proposed regulatory changes actively address this issue, or if this is an issue that requires systemic engagement.

6. Why or why not? If you are in favour of granting an exemption, please provide the explicit conditions under which an exemption should be granted and explain why an exemption is warranted.

Engineers Australia does not support a blanket exemption for assistive technologies.

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11 Therapeutic Goods Administration. 'Conformity assessment overview' Department of Health and Aged Care, Australian Government (June 2024) https://www.tga.gov.au/how-we-regulate/manufacturing/medical-devices/conformity-assessment/conformity-assessment-bodies/tga-conformity-assessment-certification/conformity-assessment-overview
12 Therapeutic Goods Administration. 'Completing a Declaration of Conformity for Class 1 medical devices' Department of Health and Aged Care, Australian Government (December 2020) https://www.tga.gov.au/resources/guidance/completing-declaration-conformity-class-1-medical-devices
13 Therapeutic Goods Administration. 'Proposed changes to the regulation of exempt medical devices and exempt Other Therapeutic Goods' Department of Health and Aged Care, Australian Government (April 2024) https://consultations.tga.gov.au/tga/proposed-changes-to-exempt-devices-and-otgs/
14 ibid

1. **Not all assistive technologies are also medical devices**. As outlined in the Preliminary Discussion, Engineers Australia broadly supports reference to and use of internationally recognised Standards (for example *AS/NZS ISO 9999: 2023* (and *ISO 9999: 2022*)) in current and future regulation of assistive technologies. However, the term assistive technologies encompasses a diverse range of products, devices, goods, instruments, systems, and software, with a similarly diverse range of risk profiles, that may or may not meet current definition of a medical device in Australian regulations. It should not be assumed that assistive technologies identified and classified within the Standard are medical devices, nor that all present the same risk classification, according to Australian regulations. All assistive technologies should be assessed against the definition of medical devices and regulated accordingly. Should TGA consider introducing a further stratification of risk levels for assistive technologies meeting the definition of a medical device (such as that detailed in the section 'Risk levels of assistive technologies'), further consultation with the sector is strongly encouraged.

2. **The TGA's identified circumstances where 'exemption' may be warranted are not sufficiently addressed.** In context of assistive technologies, Engineers Australia agrees with TGA's position that:

> *"In some circumstances it is not practical to require pre-market approval by the TGA and/or ARTG inclusion for a therapeutic good or there are existing risk mitigating strategies in place. Exemption allows these kinds of products to be continually supplied without seeking pre-market approval by the TGA or inclusion in the ARTG."* [15]

The consultation document defines circumstances where an exemption may be granted:

> *"In the case of devices and OTGs, circumstances where an exemption may be given include:*
>
> - *Where there are already suitable frameworks for the regulation of a product in place to manage risks associated with the manufacture of a product, such as where a device is manufactured as a component of clinical practice.*
> - *Where a device is not freely available on the market, such as for use in a clinical trial or for use by a visiting sporting team.*
> - *Where a device is subject to a transition period due to the introduction of new regulatory requirements, such as patient-matched medical devices that were previously custom-made and are now transitioning to inclusion in the ARTG."* [16]

For a majority of assistive technologies currently meeting the definition of a Class I, and particularly those potentially presenting more than the lowest level of risk, for example 'under-advice' assistive technologies or 'prescribed' assistive technologies as described in the Preliminary Discussion, these circumstances are not met. Assistive technologies purchased in Australia are covered by Australian Consumer Law.[17] However this law does not address pre-market activities, nor require proactive post-market vigilance by manufacturers/sponsors. It is unclear if these assistive technologies would be covered by existing medical device pathways, such as the Special Access Scheme or the Personal Importation Scheme. If not, there are no other suitable frameworks for regulation of these products, and no existing (or proposed) regulatory mechanism to manage risks associated with manufacture and supply.

15 Therapeutic Goods Administration. 'Proposed changes to the regulation of exempt medical devices and exempt Other Therapeutic Goods' (p.10) Department of Health and Aged Care, Australian Government (April 2024) https://consultations.tga.gov.au/tga/proposed-changes-to-exempt-devices-and-otgs/

16 Therapeutic Goods Administration. 'Understanding your regulatory obligations for exempt medical devices' Department of Health and Aged Care, Australian Government (June 2024) https://www.tga.gov.au/resources/guidance/understanding-your-regulatory-obligations-exempt-medical-devices

17 Australian Competition & Consumer Commission. 'Buying products and services' Commonwealth of Australia (accessed November 2024) https://www.accc.gov.au/consumers/buying-products-and-services

Should TGA consider introducing a further stratification of risk levels for assistive technologies meeting the definition of a medical device (such as that detailed in 'Risk levels of assistive technologies' section), further consultation with the sector is strongly encouraged.

3. **Exemption may exacerbate previously identified compliance concerns.** The TGA has previously identified issues with low rates of awareness and compliance with regulatory requirements associated with some exempt products. TGA has also flagged the lack of available information identifying these sponsors as further limiting TGA's ability to contact them for the purposes of education and communication[18]. Exempting all assistive technologies would further exacerbate this problem.

4. **Exemption may have limited impact on reducing costs for regulatory compliance**. While the process of registering on the ARTG is not particularly onerous for experienced medical device manufacturers/sponsors, the listing and maintenance costs may be disproportionately prohibitive for sole practitioners, SMEs, and sponsors offering numerous low-margin assistive technologies. Eliminating these costs through exemption would certainly be welcome. However, exemption impacts ARTG listing only, and does not absolve manufacturers/sponsors from requirements for regulatory compliance. ARTG registration costs may be small compared with time or cost associated with preparing comprehensive evidence (including clinical evidence) in support of compliance with the Essential Principles and developing a comprehensive procedure for post-market vigilance as described in the response to Proposal 1. Even the self-certification procedures for Declarations of Conformity will still result in increased costs for the manufacturer/sponsor, primarily for preparation and compilation of appropriate documented evidence (including clinical evidence) to satisfy the regulatory obligation to have this ready in case of request. Further, if the primary intention of an exemption in Proposal 2 is reducing financial costs associated with registration, it has potential to fundamentally to undermine and confuse the original intention of exemption across all medical devices. If this is the case it would be more appropriate to create waiver of ARTG fees for devices that are not otherwise exempt. However, it is noted that these financial costs are substantively how the TGA achieves revenue and are therefore tied to the effectiveness of the Regulator. This conflict makes the exemption mechanism problematic.

7. Do you agree that information about exempt assistive technology devices should be collected?

8. Why or why not? If there are reimbursement programs or schemes that could use information about exempt assistive technology devices, please indicate here the names of those programs/schemes and the department/body/agency/entity administering them.

Many funders of assistive technologies (for example insurers, including the NDIS, federal and state-based equipment funding schemes, and others) reference ARTG listing or registration as a requirement for funding approvals. ARTG listing may be utilised, in part, as a proxy measure to manage risks associated with manufacture and supply (such as compliance with Australian and/or International Standards). Alternative medical device supply pathways, such as the Special Access Scheme or the Personal Importation Scheme, facilitate management, tracking, and oversight of distribution and supply, which makes a public register less critical.

Further, assistive technologies, particularly those that are 'generally available', may have broader and difficult to track distribution networks which may benefit from listing sponsor information in a publicly accessible register. ARTG listing enables consumers to access important information relating to specific assistive technologies, including the manufacturer/sponsor, the intended purpose, and any conditions or restrictions for use. In general, this provides a public benefit.

[18] Engineers Australia 'Proposed changes to the regulation of exempt medical devices and exempt other therapeutic goods: submission to consultation' *Engineers Australia* (June 2024) https://www.engineersaustralia.org.au/sites/default/files/2024-07/Submission-CBME-TGA-regulation-of-exempt-medical-devices.pdf

Engineers Australia members involved in manufacture and supply of currently exempt devices (mostly low-volume patient-matched and custom medical devices) already report difficulties in receiving funding because they are not ARTG listed.

Engineers Australia supports considering alternatives to ARTG listing that address the regulatory burdens (administrative and financial) whilst maintaining visibility of exempt devices.

9. Do you agree that information about exempt assistive technology devices should be made public through a register?

10. Why or why not?

Engineers Australia supports considering alternatives to ARTG listing that address the regulatory burdens (administrative and financial) whilst maintaining maintain visibility of exempt devices.

However, Engineers Australia urges caution and assurances that will uphold protection of an individual's private information. Access to information about a medical device should not publish individual's anatomy, physiology or pathology in a way that undermines their right to privacy. This might include using information about a medical devices shape, function or intention to infer details about the user that are not otherwise apparent or publicly disclosed.

Similarly, publicly available information associated with low volume medical devices must not contain sufficient details of the supplied medical device might be used to support identity fraud (for example by contacting a supplier and using a device's unique code as evidence of identity). While companies should have sufficiently robust privacy rules to prevent this, for low volume assistive technologies, it is difficult to see the benefit of having the information publicly available in a manner that is different to current pathways (such as the Special Access Scheme or the Personal Importation Scheme).

11. If a registry of exempt assistive technology devices is established, should information be arranged by kind of assistive technology device or by manufacturer/provider/sponsor?

12. Why or why not?

Assuming that this registry will be built in a modern databasing language, and that the intention will be to collect both 'device kind' and 'responsible parties' as specified input data, it is unclear why data must necessarily be organised by one or the other, and not equally viewable in either manner. Users should be able to organise the data by various fields and filters to facilitate their search. This can be easily achieved without causing any disruption to the underlying data.

13. Do you agree that cost recovery measures should be introduced to recover TGA expenditure associated with the regulation of assistive technology devices?

14. Why or why not?

It is vitally important for the TGA to have adequate resources to effectively regulate medical devices in Australia, and to ensure that regulations stay relevant with the increasing rapid changes in medical device technologies. It is reasonable that a part of this funding should be derived from fees and charges of manufacturers and sponsors looking to bring products to market, who benefit from the consumer confidence that regulatory oversight instils. These fees and charges also create a barrier to entry that needs to balance deterring frivolous products from being put up for assessment and registration with not deterring smaller companies from market entry.

It is reasonable to apply some low-level cost recovery measures to offset the cost of regulating the medical devices, but the TGA should also have some level of secure funding from the Federal Government to enable it to be effective and not entirely reliant on charging manufacturers and sponsors. A significant proportion of the assistive technology market in Australia is currently funded through publicly funded insurance schemes including the NDIS, iCare (NSW), TAC (Vic), and similar agencies from other states and territories. As increasing fees and charges to manufacturers and

sponsors will result in a price rise of products to cover the fees and charges, which will then largely be covered by public funds, it does not make sense to apply significant cost recovery measures in favour of direct federal funding. In this case it is those clients who are not covered by insurance schemes (including a significant number of aged care clients with inadequate access to equipment funding) who will be the most disadvantaged by applying fees and charges for the purposes of cost recovery.

Boundaries – Questions

15. Do you have feedback or comments, both generally or for specific products, on assistive technologies which are appropriate for medical device regulation, and those 'boundary' products which should not be medicalised as therapeutic goods?

Removal of excluded (Proposal 1) will lead to many therapeutic goods considered as assistive technologies being regulated as a medical devices. Engineers Australia disagrees that regulating some assistive technologies as medical devices as the effect of 'medicalising' these goods. Many assistive technologies have an associated risk profile low enough to not to warrant regulatory oversight (by exclusion) or to not warrant public listing of registration details (by exemption). However, there is no clear rationale as to why all assistive technologies should be treated differently to any other medical devices, regardless of intended use or risk classification. All assistive technologies should be assessed and classified based on the device's intended purpose and risk level classification. Those devices which meet other criteria for exemption would still be exempt, while other devices would be regulated as usual.

Should TGA consider introducing a further stratification of risk levels for assistive technologies meeting the definition of a medical device (such as that detailed in Risk levels of assistive technologies section), further consultation with the sector is strongly encouraged.

Recommendations:

1. **Remove Schedule 1: Item 9:** Prepare for Schedule 1: Item 9 exclusion criteria to be removed by a given deadline. Given the current regulatory transitions that are underway it is recommended to set a removal date for 1 July 2029 to coincide with other regulatory changes coming into full effect. Proposal 1 is supported, on the condition that it is clear what mechanism will replace it.
2. **Adopt an agreed definition and classification of assistive technologies for use in regulation**. Engineers Australia broadly supports reference to and use of AS/NZS ISO 9999: 2023 for this purpose.
3. **Determine an alternative approach to reducing regulatory burden without using 'exempt':** While a reduced regulatory burden for low-risk assistive technology is supported, a blanket exemption for all assistive technologies, is not an appropriate mechanism to achieve this. A further stratification of assistive technologies according to an internationally-accepted, risk-based criteria (such as that in the Preliminary Discussion) is recommended.
4. **Supplement TGA budget with Federal funding:** It is acknowledged that the TGA is unable to be a fully effective regulator without adequate resourcing. Proposal 2 explores the option to cover operation costs through the imposition of fees and charges for assistive technologies. This is not supported due to the likely increase in equipment costs for those least able to pay. Instead of applying additional management fees, the TGA is encouraged to develop a proposal for Federal funding.

Engineers Australia appreciates the opportunity to provide its reflections and recommendations on the Consultation Paper and would welcome any further discussion on this matter if it can be of assistance.

For further information please contact Kelly Coverdale, Chair of the Biomedical College, Engineers Australia at policy@engineersaustralia.org.au.

Appendix

a) **Definitions of 'assistive technology'**
Engineers Australia recognises that multiple definitions for the term 'assistive technology' exist across research, legislation, and policy. Internationally, the term 'assistive technology' is considered an umbrella term that encompasses (a) a broad and diverse range of products, devices, goods, instruments, systems, and software, and (b) the related clinical, technical and administrative systems, services and wraparound supports needed for the safe recommendation, supply, and use (sometimes referred to as "soft technologies")[19].

b) **Standards**
ISO 9999: 2022 was identically adopted as AS/NZS ISO 9999: 2023 Assistive products for persons with disability – Classification and terminology. Going forward, Engineers Australia strongly recommends referencing the Australian / New Zealand standard, rather than the ISO standard.

c) **Risk classification**
Examples of consultations with a three-level risk classification:

a. Australian Healthcare Associates. 'Review of Assistive Technology Programs in Australia: Final Report and Supplementary Technical Report for the Australian Government Department of Health' *Department of Health* (June 2020) https://www.health.gov.au/resources/publications/review-of-assistive-technology-programs-in-australia-final-report
b. Australian Government. 'Assistive Technologies and Home Modifications Scheme for in-home aged care' *Department of Health and Aged Care* (2022) https://www.health.gov.au/resources/publications/assistive-technologies-and-home-modifications-scheme-for-in-home-aged-care?language=en

At its inception, the National Disability Insurance Scheme (NDIS) also adopted this three-level risk classification. Recently however, NDIS moved to a two-level risk approach[20]:

a. Low risk assistive technology products:
Products that can be chosen by NDIS participants and their families, that need very little advice or setup support from assistive technology advisors to use them safely. There's a low risk of causing harm when used in day-to-day life.
b. Higher risk assistive technology products:
Products that generally need advice from an assistive technology advisor or assistive technology assessor to confirm the right item selection and the best outcomes. It includes items regulated by the Therapeutic Goods Administration in Australia. Information from the NDIS Quality and Safeguards Commission also informs classification of items and products as higher risk.

This two-level risk approach makes a clear demarcation between AT products that are subject to regulatory frameworks under Australian law, and those that are not. For the workforce, it also makes a simple differentiation between AT that can potentially be supplied safely and effectively without (written) advice, and AT which would benefit from involvement of an AT Assessor. Engineers Australia does not recommend this two-level classification approach for the purpose of regulatory oversight of assistive technologies by the TGA.

d) **'Prescribed' assistive technologies**
The term "prescribed" in context of assistive technology has historically indicated a best practice recommendation for involvement of appropriately skilled and knowledgeable personnel (usually healthcare practitioners or assistive technology advisors) to facilitate

[19] Layton, N., Spann, A., Khan, M., Contepomi, S., Hoogerwerf, E. J., Bell, D., & de Witte, L. 'Guidelines for assistive technology service provision – A scoping review' Disability and Rehabilitation: Assistive Technology, 1–12 (February 2024) https://www.tandfonline.com/doi/full/10.1080/17483107.2024.2327515#abstract
[20] National Disability Insurance Agency 'Assistive technology product risk table' NDIS, Australian Government (October 2023) https://ourguidelines.ndis.gov.au/supports-you-can-access-menu/equipment-and-technology/assistive-technology/assistive-technology-product-risk-table

(clinical) assessment, selection and specification of assistive technology solutions. The term "prescribed" is also used in context of assistive technology provision by many funding providers, where appropriately skilled and knowledgeable (healthcare) practitioners or assistive technology advisors are required to provide an assessment and justification for any recommended assistive technology solutions.

There is no legislative or regulatory basis for restricting supply of assistive technologies to a person or user without written instruction of an authorised health professional. For that reason, the term here is not consistent with use in regulating prescription medicines, that is, a prescription medicine is a medicine that can only be made available to a patient on the written instruction of an authorised health professional. Engineers Australia recommends adoption of an alternative term, such as "practitioner-facilitated" or "advisor-informed" to avoid confusion with regulation and supply of prescription medicines.

e) **"People with disabilities"**

AS/NZS ISO 9999: 2023 (and ISO 9999: 2022) defines "disability" as:

3.6 Disability

Umbrella term for impairments (3.9), activity limitations (3.2) and participation restrictions (3.12) denoting the negative aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors)